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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,041	12/14/2005	Mark Roby	2873(203-3512	5860

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EXAMINER	
GILLESPIE, BENJAMIN	
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1796	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,041	ROBY, MARK	
	Examiner	Art Unit	
	BENJAMIN J. GILLESPIE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/28/2007, 11/29/2007, 1/3/2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 2-9, 13-14, 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-9, 13-14, and 21-24 are rejected because each claim is dependent on claims 1 and 17, however the language consisting of "a composition as in claim 1," and "a method as in claim 17" render the claims indefinite because it is not clear if "a composition" or "a method" correspond to the composition and method listed in claims 1 and 17.

2. Claim 20 is rejected because the language "A method of comprising," is confusing; correction is required. The terms "approximating" and "approximated" render claim 15 indefinite because it is unclear what these terms mean. Claim 24 is rejected because "partially" is a relative term.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-6, 8-9, 15-18, 20-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over English et al ('691). English et al teach a bioabsorbable tissue adhesive comprising polyester and aromatic diisocyanates, with the polyester backbone

preferably derived from lactide, glycolide, and ξ-caprolactone and initiated by 1,1,1-tris (hydroxy-methyl)ethane or ethylene glycol (Col 2 lines 60-68; col 3 lines 1-19). In particular patentees explain that the aromatic diisocyanate is present in excess by as much as a 6:1 NCO:OH ratio (Col 7 lines 63-65). Therefore, although not explicitly stated the reaction system contains isocyanate-terminated prepolymers but also additional diisocyanate monomer.

4. Although English et al teach that the bio-absorbable polyesters may be based on di or tri functional compounds, patentees fail to teach a polyurethane system that is a mixture of both. Nevertheless it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over English et al ('691) in view of Bennett et al ('130). Aforementioned, English et al teach a polyurethane adhesive comprising the reaction product of isocyanate-terminated bio-absorbable polyester prepolymers, and important to note is that English et al further teach said adhesive may contain catalyst such as 1,4-diazabicyclo [2,2,2] octane, however there is no disclosure correspond to applicants' cure time of claim 23 (Abstract).

6. Bennett et al teach an adhesive comprising a (A) bio-absorbable oligomeric ester, (B) tri-functional compound, and (C) diisocyanate, wherein (A) and (B) are terminated with isocyanate groups (Abstract; col 3 lines 39-57; col 4 lines 37-60; col 5 lines 58-67). Important to note is that Bennett et al teach the adhesive composition is cross-linked

through the aid of 1,4-diazabicyclo[2.2.2]octane, at a temperature between 20°C and 40°C, and as little as five minutes (Col 6 lines 22-37).

7. Although Bennett et al specifies that the selection of diisocyanate is important and certain aromatic diisocyanate should not be employed because of toxicity concerns, it still would have been obvious to utilize the cross-linking parameters of Bennett et al in the composition of English et al based on the motivation that Bennett et al do no limit certain diisocyanates, and the composition of English et al has been clearly disclosed for use as a living tissue adhesive and therefore is safe for in-situ applications. Another important note is that the both teach 1,4-diazabicyclo[2:2.2]octane as the cure catalyst, wherein the curing takes place in at the same temperatures, and the reactive species present during cross-linking, i.e. isocyanate groups and water, are the same.

8. Claims 1-9, 13-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipatova et al ('535) in view of English et al ('691) and Ueyanagi et al ('245). Lipatova et al teach a tissue adhesive composition comprising bioabsorbable compounds that are end-capped with aromatic diisocyanate, and aromatic diisocyanate (Col 1 lines 33-48, 66-67). Specifically, patentees explain the aromatic diisocyanate consist of 4,4'-diphenylmethane diisocyanate, naphthalene diisocyanate, and toluene diisocyanate (Col 2 lines 20-23).

9. Lipatova et al also teach a method of adhering a first and second tissue together via said composition, sealing a defect in tissue via said composition, wherein the seal prevents leakage of bodily fluids, and the composition is cross-linked through contact with water (Col 1 lines 24-26; col 4 lines 58-68; and col 9 lines 3-6). Still ,patentees fail

to teach bioabsorbable polyester that corresponds to applicants' claims and trifunctional adducts of the aromatic polyisocyanate.

10. Aforementioned, English et al teach bioabsorbable tissue adhesives comprising polyester and aromatic diisocyanates, with the polyester backbone preferably derived from lactide, glycolide, and ξ-caprolactone and initiated by pentaerythritol or ethylene glycol (Col 2 lines 60-68; col 3 lines 1-19). Patentees go on to explain that these polymers have the advantage of acting as normal constituents in metabolic pathways after being broken down by hydrolysis, and therefore are less toxic to the user (Col 2 lines 18-22).

11. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to utilize the polyesters of English et al in Lipatova et al based on the motivation that both teach bioabsorbable tissue adhesives based on polyester backbones and aromatic diisocyanates, and the polyester of English et al is less toxic for the user.

12. Ueyannagi et al teach adhesives containing tri-isocyanate functional urethane adducts of diisocyanate, which are the reaction product of tri-functional alcohols such as trimethylolpropane or glycerin and aromatic diisocyanate (Abstract; col 1 lines 5-17; col 3 lines 17-25; col 7 lines 38-40, 46-47; col 8 lines 47-50). Specifically, patentees explain that monomeric diisocyanate exhibit high viscosities thereby requiring the addition of organic solvent or heating in order to obtain a level of adequate mixing prior to application. The urethane adduct overcomes this deficiency by inherently exhibiting a lower viscosity (Col 1 lines 19-68; col 2 lines 1-56).

13. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include tri-functional urethane adducts of aromatic diisocyanate as

disclosed by Ueyannagi et al in Liptova et al based on the motivation that both are drawn to polyurethane based adhesives, the urethane adduct improves mixability without the addition of organic solvent, which is harmful in bio-applications, or pre-heating, which is undesirable because of excess pre-cure, and it is prima facie obvious to add a known ingredient for its known function; *In re Linder* 173 USPQ 356; *In re Dial et al* 140 USPQ 244.

14. Finally regarding the amounts of claims 13 and 14, although Liptova et al teach the polyester based urethane prepolymer may be present between 30 and 99% by weight of total composition, there is no teaching to as how much the diisocyanate monomer and adduct should be present. Nevertheless it would have been obvious to arrive at applicants' claimed ranges based on the presence of the adduct has an effect on the resulting viscosity of the polyurethane reaction system, i.e. the amount is a result effective variable, and it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

15. Applicant's arguments with respect to claim11/15/2007 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN J. GILLESPIE whose telephone number is (571)272-2472. The examiner can normally be reached on 8am-5:30pm.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

B. Gillespie

RABON SERGENT
PRIMARY EXAMINER